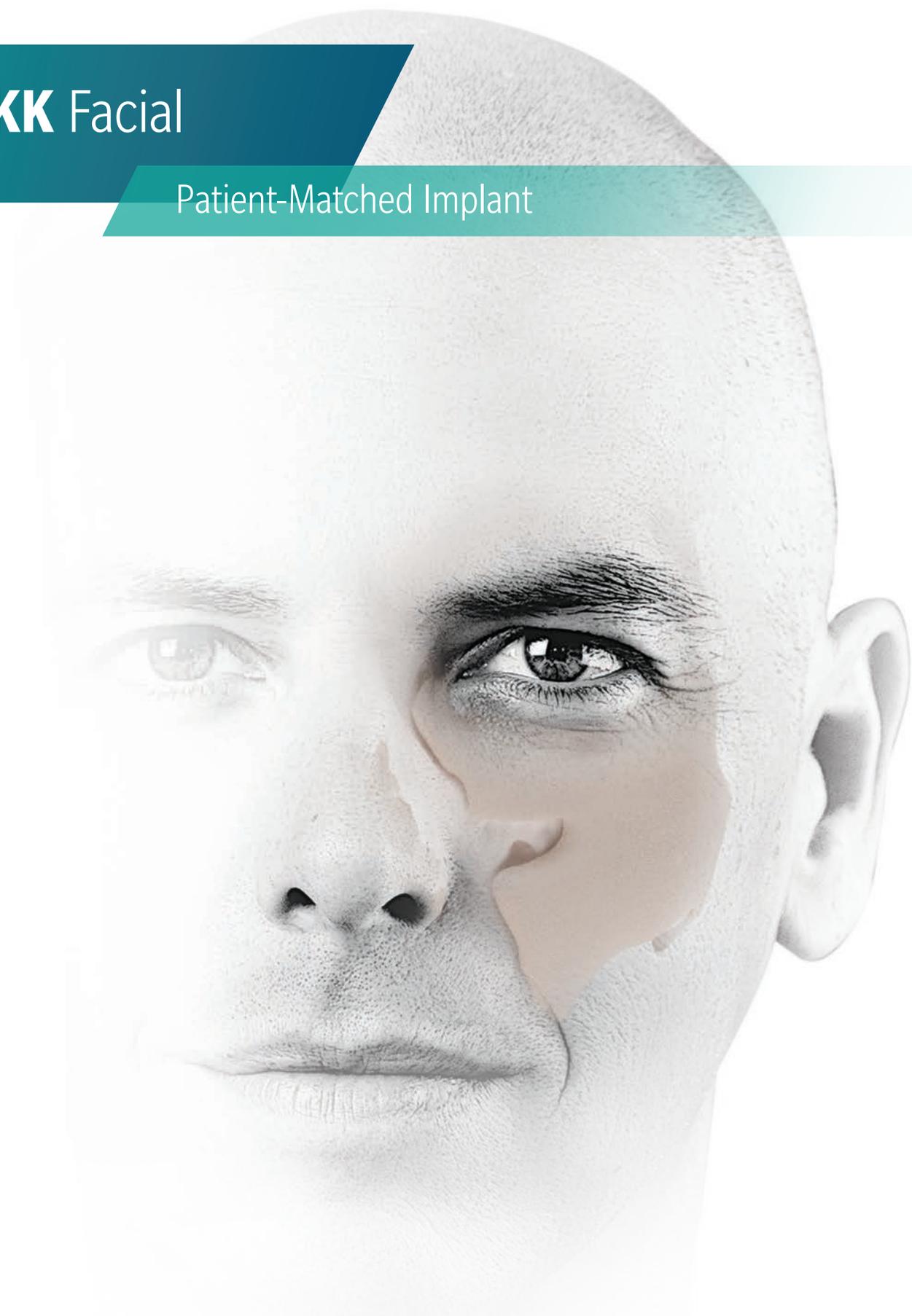


PEKK Facial

Patient-Matched Implant



CMF



Encompass PEKK-Facial is manufactured in partnership with Oxford Performance Materials (OPM) using OsteoFab™ Technology.

An innovative Patient-Matched Solution for Complex Facial Reconstruction and Augmentation

Poly-ether-ketone-ketone (PEKK) is the first 3D-printed polymer implant cleared for sale in the U.S. by the FDA.¹

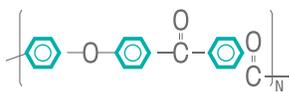
Delivering patient-matched, selective laser sintered (SLS) solutions not feasible through other conventional manufacturing methods², PEKK-Facial utilizes a unique biocompatible polymer and Virtual Surgical Planning[®] to solve the complex, organic design needs for patients across the full breadth of craniomaxillofacial specialties.

Highlights

Reduced OR time ³	Patient-Matched CMF implants with profiles as thin as 1mm ⁴
Proven biocompatibility ⁵	Textured surfaces may support on growth of new bone ⁶
Displays bone-like properties in compression strength ⁷	Simplified CT data transfer through FTP and PACS

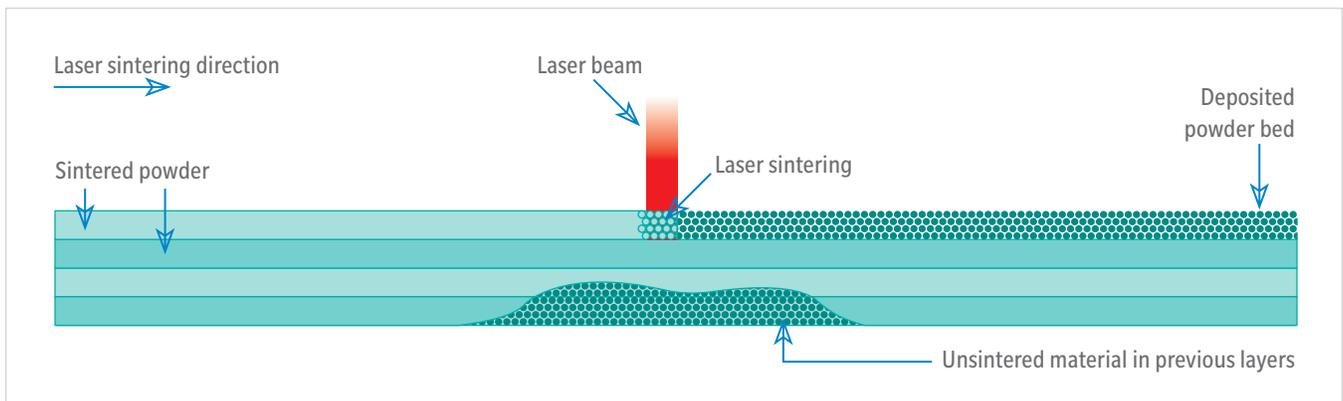
Long History as successful Material

PEKK (Poly-Ether-Ketone-Ketone) is a biocompatible material from the same PAEK polymer family as PEEK.⁸ This family of materials has been utilized in orthopedics and trauma since the 1980s.⁸ Surgeons can now select a material for medical device implants offering properties such as radiolucency⁹ and high mechanical strength.¹⁰

MECHANICAL PROPERTY	LASER SINTERED PEKK	EXTRUDED PEEK	PEKK: POLY-ETHER-KETONE-KETONE
Compressive	172 Mpa ¹¹	131 Mpa ¹²	
Tensile strength	95.8 (64) Mpa ¹¹	61 Mpa ¹²	
Screw pullout ¹³	51.1 Lbf ¹³	43.5 Lbf ¹⁴	

PEKK Manufacturing with Selective Laser Sintering (SLS) Technology

PEKK is the first laser sintered polymer device cleared for sale in the U.S.¹ The laser sintering process fuses material particles together layer-by-layer to create a lightweight implant with intricate designs. Because of the ‘printing’ technique, laser sintering allows for complexities beyond what traditional manufacturing methods can build.² This method, combined with the unique PEKK material properties, yields a true patient-matched implant with a textured or coarse surface.

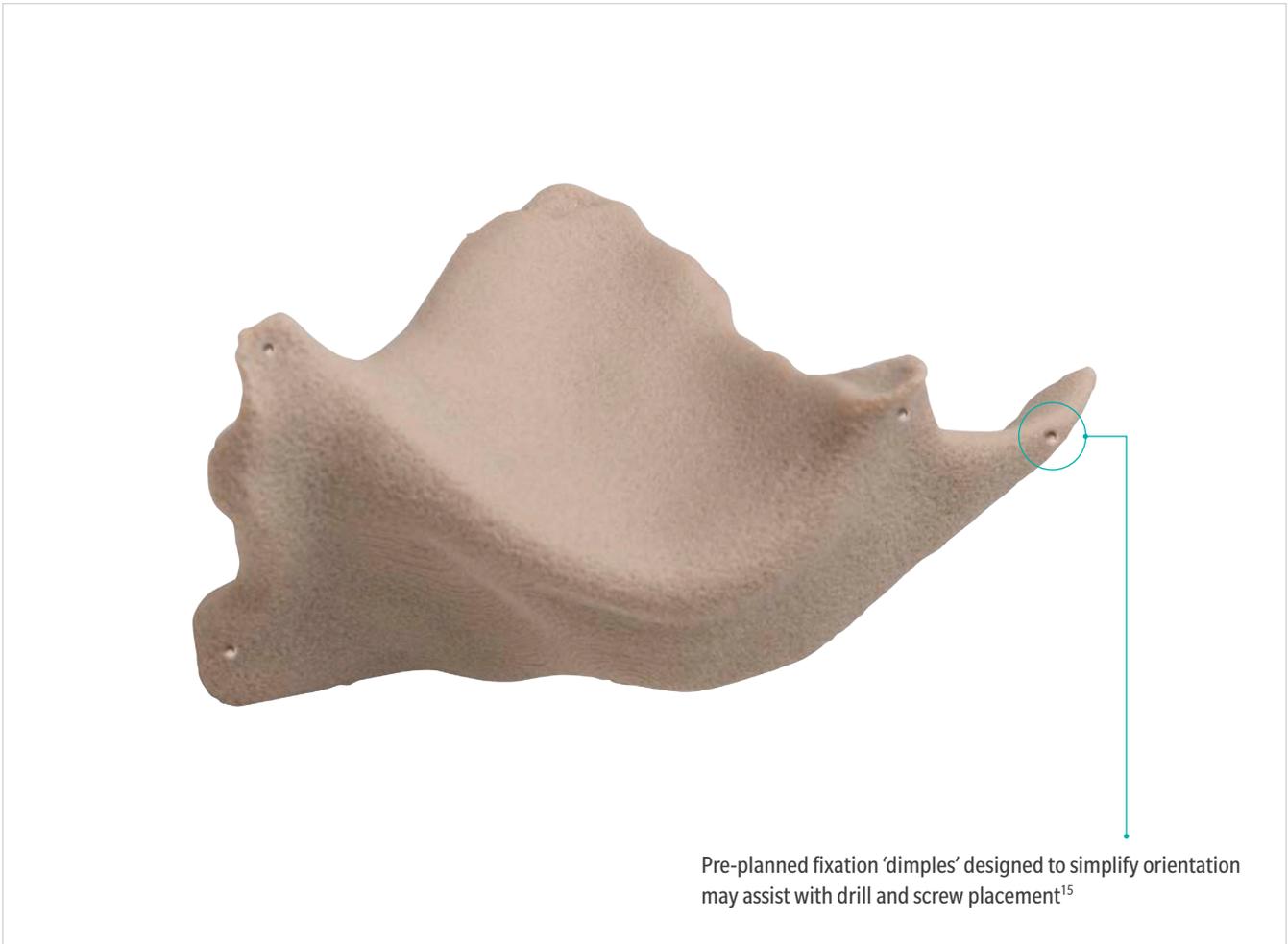


Once removed from the laser sintering machine, each implant is excavated from the PEKK powder bed by hand. The implant is then pressure cleaned to remove unsintered material. PEKK Facial implants are inspected using a white light scanner that measures within 0.002inches. The Scanner compares the final manufactured implant to the surgeon-approved design to ensure accuracy in the manufacturing process.

Indication and Application

PEKK-Facial is designed individually for each patient; from enhancements to correcting trauma and/or defects in facial bone, as well as non-load bearing enhancements of mandibular bone.⁴

<p>Accommodates Lag Techniques in both Midface and Mandible.</p>	<p>If deviations to case plan occur an implant thickness map is provided for intra-operative fixation flexibility.</p>
<p>PEKK implants can be shaped intra-operatively, if needed, using high speed rotating instruments. All shaping should be made away from the surgical site and the implant should be rinsed with saline to remove any loose particles before implantation.⁴</p>	
<p>PEKK-Facial is fixated with Zimmer Biomet’s rigid fixation screw and plating systems; including the TraumaOne™ and 1.5/2.0 CMF systems.</p>	



Bonelike Properties

Textured surface may support on growth of new bone ⁶		Lightweight with high mechanical strength ⁷	
High-Thermal Stability ¹⁶	Compression and elasticity modulus similar to human bone ⁷	Biocompatible ⁵	

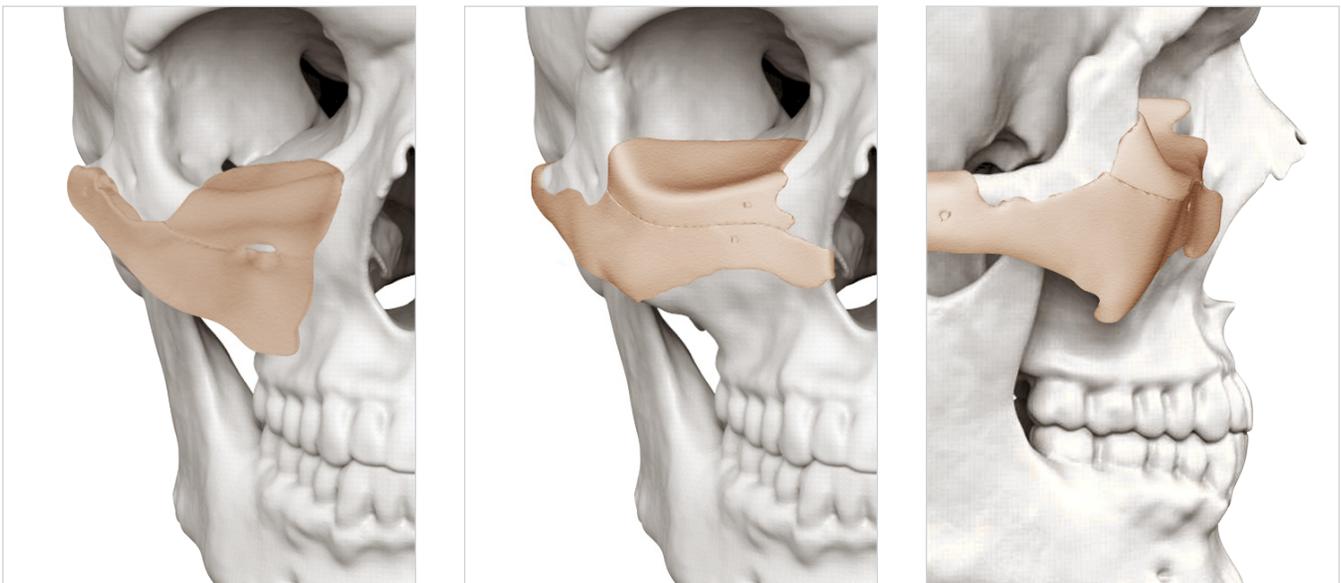
PEKK Features

- PEKK-Facial implants benefit from layers of laser-sintered polymer material resulting in bonelike compressive and tensile strengths⁷, with lower stress shielding than general metal materials.²
- With expanded design capabilities over other conventional manufacturing methods, PEKK-Facial achieves remarkably intricate solutions for patients of varying needs. Implant flexibility includes:

Thicknesses from 1mm – 10mm ⁴	Diameters of up to 20cm ⁴	Detailed implant thickness map included for fixation flexibility
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- Interactive Virtual Surgical Planning[®] for every case
- Pre-planned ‘dimples’ appear on the implant itself for intra-operative orientation and to ensure adequate material thickness is present at points of fixation.
- Fixation dimples may aid in drilling and screw placement.¹⁵

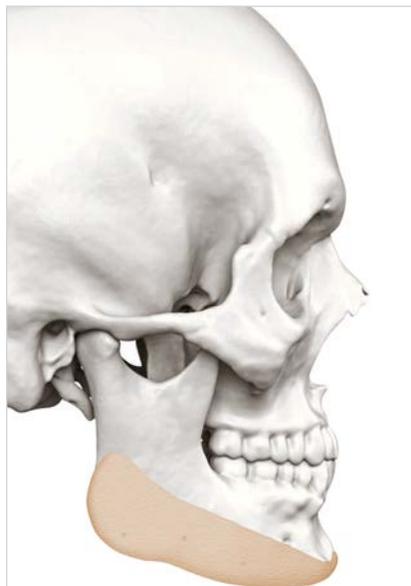
Orbital Floor and Zygoma Reconstruction



Upper Orbital Rim Reconstruction



Midface Reconstruction

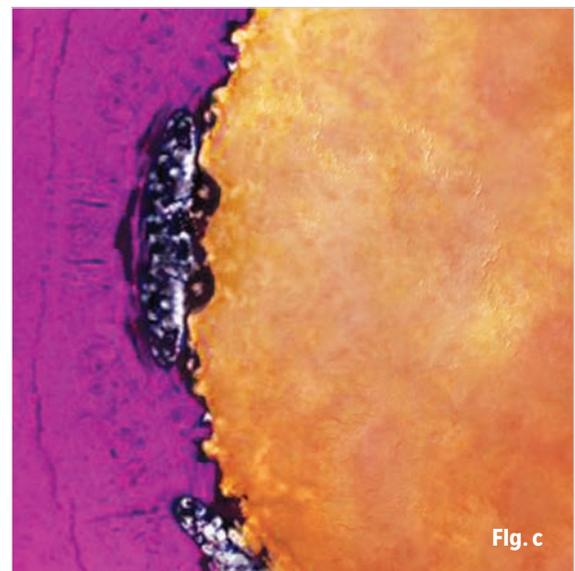
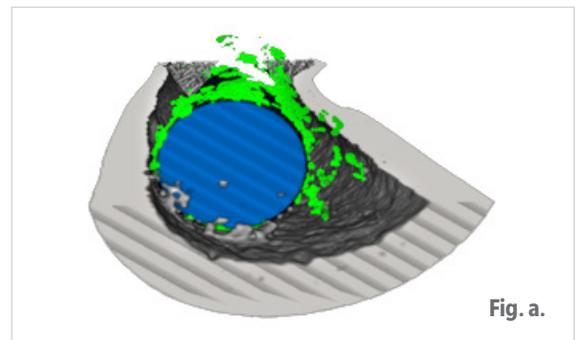
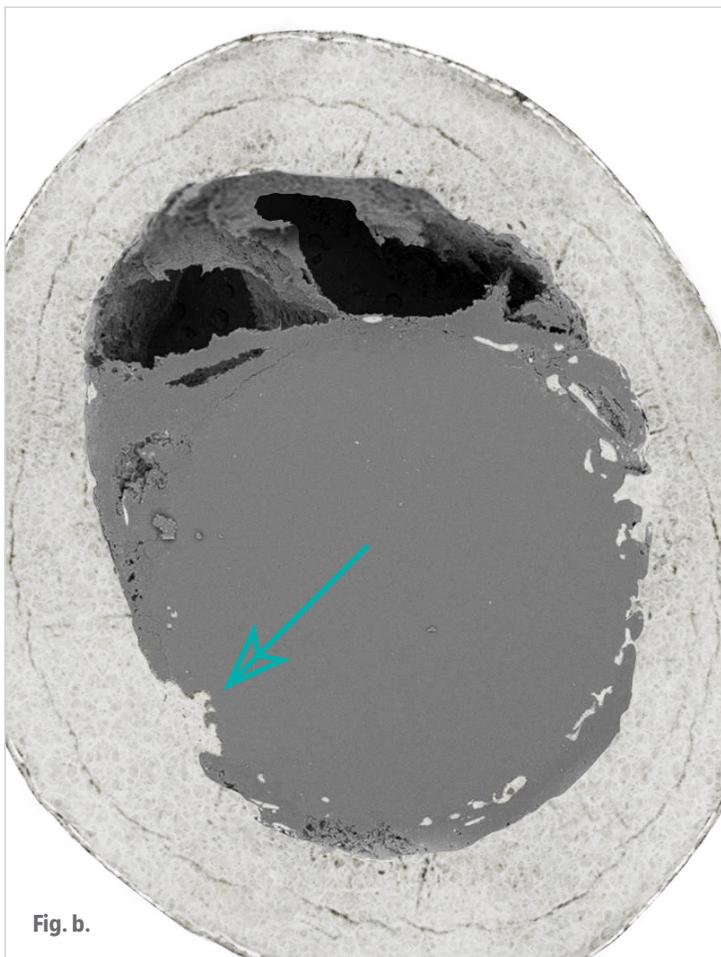


Mandible Augmentation



PEKK Animal Study⁶

In a recent rabbit femur study, 13 out of 13 PEKK implants with varying surface textures displayed on growth of new bone out to 12-weeks. Included in the study was a select laser sintered PEKK implant similar to that of PEKK-facial (Fig. a, b, c).



At 12-weeks formation of new bone around the SLS PEKK implant was observed without the growth of fibrous tissue at the bone/implant interface. Top view of new bone growth around the PEKK implant (**Fig. a**). Representative cross section microscopy image with arrow showing area of histology (**Fig. b**). Histological image showing new boney (magenta) on growth at PEKK implant interface (brown) (**Fig. c**).

NOTE: Animal testing may not be indicative of clinical performance. Study photos courtesy of Oxford Performance Materials

Sterilization Recommendations⁴

European Norms (EN)	International Standards (ISO)	World Health Organization (WHO)
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Sterilization Standards⁴

	PRE-VACUUMED STEAM STERILIZATION (HI-VAC) WRAPPED	GRAVITY DISPLACEMENT STEAM STERILIZATION WRAPPED
TEMPERATURE	270° F - 279° F (132° C - 137° C)*	275° F (135° C)
TIME	Four (4) Minutes*	Ten (10) Minutes
DRYING TIME	Thirty (30) Minutes MINIMUM	Thirty (30) Minutes MINIMUM

*For countries outside the USA, expanded temperature range and sterilization time may be increased to 18-minutes so as to comply with recommendations from the WHO

¹OPM Receives FDA Clearance for 3D Printed OsteoFab Patient-Specific Facial Device. OPM. Oxford Performance Materials, 19 Aug. 2014. Web. 26 July 2017. • ²Nakano, Takayoshi, and Takuya Ishimoto. "Powder-based Additive Manufacturing for Development of Tailor-made Implants for Orthopedic Applications." KONA Powder and Particle Journal No. 32 (2015)32 (2015): 75-84. Web. 26 July 2017. • ³Singare, Shenggui S. "The Benefit of 3D Printing in Medical Field: Example Frontal Defect Reconstruction." Journal of Material Sciences & Engineering 1000335th ser. 6.2 (2017): n. pag. Web. • ⁴QMSL-6005 Cranial Facial IFU 2015Oct28 (PEKK-Facial IFU) • ⁵ISO 10993 – OPM 15 Test Report • ⁶R2016Sep14-02 R abbit Femur Osseointegration Report 2016Nov02 • ⁷QMSL-5007 Rev 1 MPC Matrix OPM ©2015Nov18. • ⁸Kurtz, S. M., and J. N. Devine. "PEEK Biomaterials in Trauma, Orthopedic, and Spinal Implants." National Center for Biotechnology Information. U.S. National Library of Medicine, Nov. 2007. Web. 26 July 2017. • ⁹Converse, Gabriel, Timothy Conrad, Christina Merrill, and Ryan Roeder. "Hydroxyapatite whisker-reinforced polyetherketoneketone bone ingrowth scaffolds." Elsevier. ScienceDirect, 6 Aug. 2009. Web. 26 July 2017. • ¹⁰ASTM F2820 - 12." ASTM International - Standards Worldwide. N.p., n.d. Web. 26 July 2017. • ¹¹OPM material specs, on file. OsteoFab™ Medical Parts and Implants. • ¹²OPM material specs, on file. OXPEKK® vs. PEEK Comparison. • ¹³Biomet Internal Test Report LT1294. • ¹⁴Biomet Internal Test Report LT1296. • ¹⁵Biomet Internal Test LT1531B. • ¹⁶Polymer Properties Database. Properties of Polyetherketones. N.p., 2015. Web. 26 July 2017. • ¹⁷Nakano, Takayoshi, and Takuya Ishimoto. "Powder-based Additive Manufacturing for Development of Tailor-made Implants for Orthopedic Applications." KONA Powder and Particle Journal No. 32 (2015)32 (2015): 75-84. Web. 26 July 2017.

WHAT IS ENCOMPASS™ ?

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with Virtual Surgical Planning® from 3D Systems



LOWER O.R. TIMES

with Patient-Matched solutions





STREAMLINED LOGISTICS

to ensure implants arrive on time for surgery



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For more information on PEKK, please call our HTR hotline at 904.741.9242 or contact us at:

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